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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,711	07/27/2001	Carlota Vinals y de Bassols	BM45324	7936

25308 7590 05/07/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)
	09/701,711	Y DE BASSOLS, CARLOTA VINALS
	Examiner Padmavathi v Baskar	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10/22/03.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 61-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 61-64 and 66-68 is/are rejected.
- 7) Claim(s) 65 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

Art Unit: 1645

Response to Amendment

1. The amendment filed on 1/29/03 has been entered into the record. Claims 61, 67 and 68 have been amended. Claims 61-68 are pending.
2. Applicant elected Group 1 claims 61-68 drawn to a polypeptide, fusion protein and immunogenic composition comprising SEQ.ID.NO: 2 without traverse in paper # 9. However, applicant has not restricted the elected invention to SEQ.ID.NO: 2. Therefore, applicant is advised to restrict the claims to SEQ.ID.NO: 2.

Rejections Withdrawn

3. In view of amendments to claims 61, 67 and 68, the rejection under 35 U.S.C. 112, second paragraph is withdrawn for claims 61-68.
4. In view of amendments to claims 61, 67, the rejection under 35 U.S.C. 102(b) as being anticipated by Blattner et al 1997 (Accession number A 64742) is withdrawn for claims 61, 63, and 67.

Rejection Maintained

5. The rejection of claims 61-64 under 35 U.S.C. 102(b) as being anticipated by Bartos et al 1988(J.Infec.Dis, 158; 761-765) is maintained as set forth in the previous office action.

Claims are directed to an isolated polypeptide comprising member selected from the group consisting of (a) the amino acid sequence SEQ.ID.NO: 2 and (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2 wherein the isolated polypeptide, when administered with a carrier induces an antibody or T-cell mediated immune response to a polypeptide having the SEQ.ID.NO: 2.

Bartos et al disclose an isolated polypeptide, outer membrane proteins i.e., OMP from whole cell lysate ATCC strain and other clinical isolates of *M.catarrhalis* (page 762, left and figure 1). Applicant's use of the open-ended term "comprising" and "fragments" in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed isolated polypeptide, OMP from *M.catarrhalis*. The isolated OMP from *M.catarrhalis* inherently comprise fragments of SEQ.ID.NO: 2 or 4 See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art outer membrane protein read on the claimed isolated polypeptide. Since the Office does not have the facilities for examining and comparing

Art Unit: 1645

applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2 with the polypeptide of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Applicants' arguments filed on 1/29/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that the recited prior art of record does not anticipate the claimed invention and does not disclose any particular polypeptide or much less that of SEQ.ID.NO: 2 and cites MPEP 2131 for support.

The examiner would like to clarify that claims 65 and 66 are not rejected as applicant states in the response. The examiner is viewing the claims as if they recite only SEQ.ID.NO: 2 since this was an elected invention.

It is the position of the Examiner that applicant failed to show that the disclosed outer membrane proteins do not contain an isolated polypeptide comprising SEQ.ID.NO: 2 and a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2. The examiner rejected the claims based on inherency since the outer membrane proteins contain several proteins that include isolated polypeptide comprising SEQ.ID.NO: 2 and a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2 and other *M.catarrhalis* antigens.

There is nothing on the record to show the differences between the claimed isolated polypeptide comprising SEQ.ID.NO: 2 and the disclosed OMPs. Therefore, the prior art reads on an isolated polypeptide comprising a member selected from the group consisting of (a) the amino acid sequence SEQ.ID.NO: 2 and (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2.

Art Unit: 1645

Applicant states that Bartos et al disclose outer membrane proteins from particular strains of *M. catarrhalis*.

It is the position of the Examiner that the applicant is arguing a limitation which is not set forth in the claims. Therefore, this rejection is maintained.

New Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 61- 64 and 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Helminen et al 1994 (J.Infec.Dis, 170; 867-872).

The claims are directed to an isolated polypeptide comprising a member selected from the group consisting of (a) the amino acid sequence SEQ.ID.NO: 2 and (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2 wherein the isolated polypeptide, when administered with a carrier induces an antibody or T-cell mediated immune response to a polypeptide having the SEQ.ID.NO: 2. The claims are also drawn to a fusion protein comprising said isolated polypeptide and an immunogenic composition comprising said isolated polypeptide in a pharmaceutically acceptable carrier. The immunogenic composition further comprises one other *Moraxella* antigen.

Helminen et al, 1994, disclose outer membrane proteins i.e., OMPs prepared from *M.catarrhalis* cells by EDTA buffer method. Monoclonal antibodies were produced by

Art Unit: 1645

immunizing mice (page 868, left column under production of Mabs) with OMPs. Applicant's use of the open-ended term "comprising" in claim 61 fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed isolated polypeptide, OMPs from *M.catarrhalis*. As OMPs comprise many proteins together it would read on fusion protein comprising said peptides and one other Moraxella antigen. Since monoclonal antibodies were raised against OMPS by immunizing the mice with OMPs in a buffer, the examiner considers the OMPs in a buffer as an immunogenic composition comprising said polypeptide in a pharmaceutically acceptable carrier. Therefore, the claimed polypeptides, fusion proteins and immunogenic compositions as claimed are inherent in the preparation of OMPs. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art OMPs read on the claimed invention. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2 with the OMPs of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

8. Claims 61-64 and 66-68 are rejected.

Claim 65 is objected to as it depends from a rejected base claim.

Art Unit: 1645

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

5/1/03

hb

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600